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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,369	09/11/2003	Dennis L. Panicali	700953-54440	5464

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EXAMINER	
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ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,369	PANICALI ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 11 September 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7 are pending and under consideration in the instant application. An action on the merits follows.

Inventorship

Applicant's petition under 37 CFR 1.48(a) filed on 12/12/05 has been entered and is granted. In view of the papers filed 12/12/05, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding Jeffrey Schlom as an inventor.

Specification

A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because the specification as filed contains two separate sections for experimental results. Experiments 1-19 are set forth on pages 26-43. This is followed by a recitation of "internally cited" references, additional disclosure, and additional experiments numbered 1-4 on pages 58-63. Therefore, the specification lists two different sets of experiments as Experiments 1-4. It is

also noted that this disjointed layout of the specification is confusing. It is suggested that the applicant consolidate the experimental sections into a single section where the experiments are all numbered consecutively.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

In addition, please noted that the listing of references in the specification, see for example pages 43-44, is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7 each recite neoplastic cell(s) which is/are "representative" of cells constituting a tumor of interest. It is unclear what characteristics make a particular cell "representative" of cells in a tumor. Are they structural, functional, or chemical properties? The specification does not provide a specific definition of what constitutes a neoplastic cell "representative" of other tumor cells. As such, the metes and bounds of the claims cannot be determined.

Claims 1-7 each further recite "at least one extra nucleotide segment comprising a viral vector and not less than one DNA sequence encoding" B7.1, ICAM-1, and LFA-3. The limitation "not less than one DNA" is confusing. Less than one would be zero. Thus, it is unclear what limitation on the DNA the applicant is trying to recite in this claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO00/34494 (6/15/00), hereafter referred to as Hodge et al. The applicant claims a genetically altered neoplastic cell or cells "representative" of cell(s) of a tumor of interest transduced with a viral vector carrying a DNA sequence encoding B7.1, ICAM-1 and LFA-3, methods of making the cells comprising transducing the cells with a viral vector encoding B7.1, ICAM-1 and LFA-3, and methods of preventing or treating a tumor in mammal by administering the transduced cell(s).

Hodge et al. teaches a recombinant viral vector encoding all of the co-stimulatory molecules B7-1, ICAM-1, and LFA-1 (referred to as TRICOM), and methods of using the vector to transduce tumor cells such that the transduced cells express all three of the encoded co-stimulatory proteins (Hodge et al., pages 1, 8, 25-26, 40, 42-43, examples 1-21, especially example 23, and claims 1-38, 42, 46-52, 55-61, 63). Hodge et al. also teaches methods of enhancing immune responses, particularly CD4 and CD8 T cell responses, to a target cell such as a tumor by administering tumor cells transduced with the recombinant vector (Hodge et al., pages 10, 22, 39, example 27, and claims 94-98). Hodge et al. further teaches that the transduced tumor cells can be introduced into the host to inhibit tumor growth (Hodge et al., pages 38, 40, 42-43). In addition, Hodge et al. teaches that transduced tumor cells of a particular type of tumor

to be prevented can be administered to a host to prevent the formation of a tumor (Hodge et al., pages 38, 40, 42-43, and claims 94-98). In particular, Hodge et al. teaches that the transduced tumor cells either express endogenously or have been modified to present or express tumor antigen specific to the tumor to be prevented/treated (Hodge et al., pages 42-43, and claims 94-98). Such tumor cells appear to be "representative" of a tumor to be treated as they express the same tumor antigens or are the same type of tumor. Thus, by teaching all the limitations of the claims as written, Hodge et al. anticipates the instant invention as claimed.

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,969,609 (11/29/05), hereafter referred to as Schlom et al.

The applied reference has two common inventors with the instant application, Jeffrey Schlom and Dennis Panicali. The patent and the instant application do not appear to be commonly owned. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The applicant claims a genetically altered neoplastic cell or cells "representative" of cell(s) of a tumor of interest transduced with a viral vector carrying a DNA sequence encoding B7.1, ICAM-1 and LFA-3 (referred to as TRICOM), methods of making the cells comprising transducing the cells with a viral vector encoding B7.1, ICAM-1 and LFA-3, and methods of preventing or treating a tumor in mammal by administering the transduced cell(s).

Schlom et al. teaches a recombinant viral vector encoding all of the co-stimulatory molecules B7-1, ICAM-1, and LFA-1, and methods of using the vector to transduce tumor cells such that the transduced cells express all three of the encoded co-stimulatory proteins (Schlom et al., columns 1, 5-6, 28-29, examples 1-21, and 23, and claims 1-3, 14-18). Schlom et al. also teaches methods of enhancing immune responses, particularly CD4 and CD8 T cell responses, to a target cell such as a tumor by administering tumor cells transduced with the recombinant vector (Schlom et al., columns 7, 26-29, and examples 24-27). Schlom et al. further teaches that the transduced tumor cells can be introduced into the host to inhibit tumor growth (Schlom et al., columns 26-27). In addition, Schlom et al. teaches that transduced tumor cells of a particular type of tumor to be prevented can be administered to a host to prevent the formation of a tumor (Schlom et al., columns 26-27). In particular, Schlom et al. teaches that the transduced tumor cells either express endogenously or have been modified to present or express tumor antigen specific to the tumor to be prevented/treated (Schlom et al., columns 27, 29). Such tumor cells appear to be "representative" of a tumor to be treated as they express the same tumor antigens or are the same type of tumor. Thus, by teaching all the limitations of the claims as written, Schlom et al. anticipates the instant invention as claimed.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all

official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER